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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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2292 7590 10/30/2002

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

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| EXAMINER |
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BADIO, BARBARA P

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 10/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,338

Applicant(s)

ARMBRUSTER, FRANZ PAUL

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 16-20, 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 15 and 21-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Non-Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claims 14 and 16-26 under 35 USC 112, second paragraph is withdrawn.

3. The rejection of claim 15 under 35 USC 112, second paragraph is maintained.

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Applicant argues that the claims are part of the specification and, thus, any language that occurs in the claims as originally filed is given the same priority date as anything that occurs in the written description. Applicant's argument was considered but not persuasive for the following reasons.

The examiner agrees that the claims as originally filed are part of the originally filed specification. However, the claimed invention should find support in the specification and, the instant claim does not. It is suggested that applicant incorporate the claim language into the present specification.

- W* 4. Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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W The instant claims recite "[m]ethod for the quantitative detection of 25-hydroxy-**and** 1 α ,25-dihydroxy vitamin D metabolite". Can the claimed method be utilized for detection of one of 25-hydroxy- **or** 1 α ,25-dihydroxy vitamin D metabolite? Is it useful only in detection of said vitamin D derivatives when both are present in the sample? The present specification indicates detection of either compound in a sample.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of claims 21-24 under 35 USC 102(e) over Holick (WO 97/24127) is withdrawn.

Note: Withdrawal is based on error made on section of 35 USC 102 referred to in previous Office Action.

7. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Holick (WO 97/24127).

Holick teaches the production of non-radioactive vitamin D compounds and their use in assaying for the presence of vitamin D and its derivatives (see the entire article,

especially pages 6-8; page 9, line 28 – page 10, line 24; claims 19-24 and Fig. 6). The method taught by the reference is encompassed by the instant claims.

Response to Arguments under 35 USC 102

8. Applicant's arguments filed August 7, 2002 have been fully considered but they are not persuasive.

Applicant's arguments were not persuasive for the following reasons:

Claim 21 is an assay method for the presence of 25-hydroxy- and 1 α ,25-dihydroxy vitamin D metabolite utilizing a vitamin D compound as defined by claim 14.

Applicant argues the prior art does not disclose compounds of formula II of the present invention. The compounds of claim 14 are not limited to those of formula II as defined on page 7 of the present specification. The claimed assay is encompassed by the cited reference because both the claimed and the prior art assays utilize 25-hydroxy or 1,25-dihydroxy vitamin D labeled compounds as defined by claim 14 in the detection of vitamin D compounds.

Applicant arguments that (a) the "biotin groups" are not biotin but another hetero ring system and (b) the disclosure of the prior art is not enabled are noted. However, example 6 of the reference provides the correct structure of biotin and, thus, the skilled artisan in the art would recognize the error in the other structures. In response to applicant's argument of a nonenabled disclosure, (a) '779 is a US patent and, thus, is considered enabled for what is disclosed and (b) '127 is enabled because it discloses method by which the starting compounds are made and starting compound, 25-OH-D₃-

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aminopropyl ether was known in the art at the time of the invention (see attached references, Swamy et al., (1995) and Roy et al., (1995). In addition, ether production is well known in the art and, thus, production of the prior art starting compound(s) would be within the level of skill of the ordinary artisan in the art.

Allowable Subject Matter

9. Claims 14, 16-20, 25 and 26 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:

Although, the Swamy et al. and Roy et al. teach the production of 25-OH-D₃-aminopropyl ether, they do not teach formation of lithium alcoholate before reduction of the nitrile group with lithium aluminum hydride as claimed by the present invention.

Other Matters

11. Applicant's statement of a comparison between the biotin shown in the instant invention and the biotin of the cited reference is noted. It is noted that said comparison was not attached to the response filed August 7, 2002.

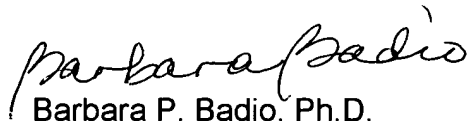
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Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
October 28, 2002